SEP 1 9 2001 K003620

510(k) Summary

Name/Address of Submitter: NSI, Inc., **T/A Northern Implants**
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Contact Person: Greta M. Hols
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Date Summary Prepared: October 27, 2000

Device Name: Endosseous Implant and Accessories

Trade Name: NSI Hexed and Non-Hexed Implant System

Predicate Devices: K951111 Restore Self-Tapping Dental Implant System
K944068 Restore Self-Tapping Dental Implant System
K874590 Innovative Implants and Cover Screws
K894594 Bonefit Hollow Screw Implants
K925773 Branemark System Gold Cylinders and Screws

Device Description and Intended Use: The NSI Hexed and Non-Hexed Implant system consists of bone screws and accessories intended for use in stabilizing a fixed or removable dental prosthesis in a single tooth, a partially edentulous prosthesis, or full arch prosthesis.

Technological Characteristics: The physical properties of the NSI Hexed and Non-Hexed Implant System with a legally marketed predicate device.
The technological characteristics were comparable.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Conclusions Drawn: The NSI Hexed and Non-Hexed Implant System has the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Greta M. Hols
NSI, Incorporated
10565 Lee Highway, Suite 100
Fairfax, VA 22030

SEP 1 9 2001

Re: K003620
Trade/Device Name: NSI Implant System
Regulation Number: 21 CFR 872.3640
Regulatory Class: III
Product Code: DZE
Dated: October 27, 2000
Received: November 22,2000

Dear Ms. Hols:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 80) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K0003620

Device Name: Endosseous Dental Implant System

Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses.

Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ OR Over-the-counter Use _____.
(Per 21 CFR801.109)

Gerald W Shipley for MSR
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003620